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Bristol-Myers Squibb Company

September 8, 2004

Dockets Management Branch
Food and Drug Administration, HFA-305
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 2004N-0018; Proposed Rule, Human Subject Protection; Foreign Clinical Studies not Conducted Under an Investigational New Drug Application; 69 Federal Register 32467 (June 10, 2004)

Dear Sir or Madam:

Bristol-Myers Squibb (BMS), a diversified worldwide health and personal care company with principal businesses in pharmaceuticals, infant formulas, and nutritional products, is pleased to have the opportunity to offer comments on the proposed rule. Our company's mission is to extend and enhance human life by providing the highest-quality pharmaceutical and related health care products. For this reason, we are interested in commenting on the above listed proposed rule. Our comments are set forth below.

Summary of BMS Comments on Proposal

We commend the *U.S. FDA* for proposing this rule that would remove the reference to the Declaration of Helsinki from the IND regulations and replace it with the requirement that the studies be conducted in accordance with good clinical practice (GCP). We agree that this change will update the standards for the acceptance of IND foreign studies and to help ensure the quality and integrity of data obtained from such studies. There are, however, several aspects of the proposed rule that appear contrary to the FDA's stated objectives, which we have cited below:

21CFR312.3 – Definition and Interpretations, Independent Ethics Committee (IEC)

We request that the definition for an "IEC" as defined in the glossary (1.27) in the Guideline for Good Clinical Practices be used so that we are consistent with existing definitions.

21CFR312.120 (3) (b) (6): The Names and Qualifications for the Members of the IEC that Reviewed the Study

We request in lieu of providing a listing of members that a statement from the IEC that they are properly constituted be allowed. This statement would indicate that IEC is properly constituted within the applicable laws that they must follow. Another concern in providing member names is the issue of privacy, and in certain countries this information may not be available due to the potential for violating privacy laws by releasing this information.

21CFR312.120 (3) (b) (11): Copies of Written Commitments, if any, by Investigators to Comply with GCP and the Protocol

The investigators signature is obtained after reviewing and agreeing to follow the commitments of the protocol which includes adherence to GCP. The need for submission of an individual form for each investigator is not warranted, since this information has been already obtained by the sponsor.

BMS appreciates the opportunity to provide comment and respectfully requests that the *FDA* give consideration to our recommendations. We would be pleased to provide additional pertinent information as may be requested.

Sincerely,

Richard L. Wolgemuth, Ph.D.
Senior Vice President
Global Regulatory Sciences